NOT FOR PUBLICATION

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

SHIRE LABORATORIES, INC.,	:	
Plaintiff,	:	Civil Action No. 06-2266 (SRC)
v.	:	**OPINION**
COREPHARMA, LLC.,	:	
Defendants.	:	

CHESLER, U.S.D.J.

This matter comes before the Court on the applications by Plaintiff Shire Laboratories, Inc. ("Shire") and Defendant Corepharma, LLC ("Corepharma") for claim construction to resolve disputes over the construction of four claim terms in U.S. Patent No. 5,326,570 ("the '570 patent"). Nostrum Pharmaceuticals, Inc. ("Nostrum") filed an amicus brief and response. This Court has examined the disputes over construction of these claim terms and, for the reasons stated below, resolves these disputes by rejecting the limitations proposed by Shire on the term "unit" and also rejecting the limitations proposed by Corepharma and Nostrum on the terms "immediate release unit[,]" "sustained release unit[,]" and "enteric release unit[.]"

I. BACKGROUND

This case arises out of an action for patent infringement. Shire owns the '570 patent, which covers a drug delivery system for the oral administration of carbamazepine. Prior to the expiration of the '570 patent, Corepharma filed an Abbreviated New Drug Application ("ANDA") with the FDA seeking to engage in the manufacture, use, and sale of extended-release

capsules containing carbamazepine. Shire contends that Corepharma's ANDA infringes the '570 patent.

On September 17, 2007, in consultation with this Court, Magistrate Judge Patty Shwartz ordered Markman briefing on the terms "unit[,]" "immediate release[,]" "sustained release unit[,]" and "enteric release unit" as used in the '570 patent. (Sept. 17, 2007 Order, docket item #129.) The parties subsequently submitted briefing concerning disputes over the construction of the four terms (words or phrases) in twenty-five claims in the one patent at issue.

There are two independent claims within the '570 patent that use these four terms, Claim 1 and Claim 18. Claim 1 reads:

> 1. A drug delivery system for the oral administration of carbamazepine, comprising:
>
> (a) a sustained release unit containing carbamazepine;
>
> (b) an immediate release unit containing carbamazepine; and
>
> (c) an enteric release unit containing carbamazepine, said combination of components (a), (b), and (c) containing a therapeutically effective amount of carbamazepine.

(Decl. of Porter F. Fleming, Esq. in Supp. of Shire's Opening Claim Construction Brief Ex. 1, 8:1-9 [hereinafter Fleming Decl.].) Claim 18 reads:

> 18. A method of treating a patient with carbamazepine comprising: orally administrating to said patient a composition which contains,
>
> (a) an immediate release unit containing carbamazepine;
>
> (b) a sustained release unit containing carbamazepine;
>
> (c) an enteric release unit containing carbamazepine; said components (a), (b), (c) containing a therapeutically effective amount of carbamazepine.

(Fleming Decl. Ex. 1, 8:60-68.)

II. LEGAL STANDARD

Claim construction is a question of law for determination by the Court. Markman v. Westview Instruments, Inc., 517 U.S. 370, 372 (1996) ("the construction of a patent, including terms of art within its claim, is exclusively within the province of the court"). A court's determination "of patent infringement requires a two-step process: first, the court determines the meaning of the disputed claim terms, then the accused device is compared to the claims as construed to determine infringement." Acumed LLC v. Stryker Corp., 483 F.3d 800, 804 (Fed. Cir. 2007).

The focus of claim construction is the claim language itself:

> [i]t is a bedrock principle of patent law that the claims of a patent define the invention to which the patentee is entitled the right to exclude. Attending this principle, a claim construction analysis must begin and remain centered on the claim language itself, for that is the language the patentee has chosen to "particularly point[] out and distinctly claim[] the subject matter which the patentee regards as his invention."

Innova/Pure Water, Inc. v. Safari Water Filtration Sys., 381 F.3d 1111, 1115-1116 (Fed. Cir. 2004) (citations omitted). The analysis of that language begins with determining the "ordinary and customary meaning of a claim term[, which] is the meaning that the term would have to a person of ordinary skill in the art in question at the time of the invention, i.e., as of the effective filing date of the patent application." Phillips v. AWH Corp., 415 F.3d 1303, 1313 (Fed. Cir. 2005). Further, the language should not be read solely in the context of the claim under review; instead, it should be analyzed "in the context of the entire patent" and with an understanding of how that language is used in the field from which the patent comes. Id. In conducting this review, a different interpretation is placed on a term located in an independent claim than on

those located in dependent claims, and it is understood that each claim covers different subject matter. Saunders Group, Inc. v. Comfortrac, Inc., 492 F.3d 1326, 1331 (Fed. Cir. 2007) (quoting Phillips, 415 F.3d at 1315 ("the presence of a dependent claim that adds a particular limitation gives rise to a presumption that the limitation in question is not present in the independent claim." id.).)

In order to review the language in this light, "the court starts the decisionmaking process by reviewing the same resources as would [a person of ordinary skill in the art in question], *viz.*, the patent specification and the prosecution history." Phillips, 415 F.3d. at 1313 (quoting Multiform Desiccants, Inc. v. Medzam, Ltd., 133 F.3d 1473, 1477 (Fed. Cir. 1998). When "the ordinary meaning of claim language as understood by a person of skill in the art [is] readily apparent[,]" understanding claim construction "involves little more than the application of the widely accepted meaning of commonly understood words." Id. at 1314. "In such circumstances, general purpose dictionaries may be helpful" to explain the terms used. Id.

However, often, the ordinary meaning of the claim language is not readily apparent, and in those circumstances,

> because patentees frequently use terms idiosyncratically, the court looks to "those sources available to the public that show what a person of skill in the art would have understood disputed claim language to mean." Those sources include "the words of the claims themselves, the remainder of the specification, the prosecution history, and extrinsic evidence concerning relevant scientific principles, the meaning of technical terms, and the state of the art."

Id. at 1314 (citations omitted).

The specification is of utmost importance in providing framework for understanding the

claim language:

> [c]laims must be read in view of the specification, of which they are a part. The specification contains a written description of the invention that must enable one of ordinary skill in the art to make and use the invention. For claim construction purposes, the description may act as a sort of dictionary, which explains the invention and may define terms used in the claims. As we have often stated, a patentee is free to be his own lexicographer. The caveat is that any special definition given to a word must be clearly defined in the specification. The written description part of the specification itself does not delimit the right to exclude. That is the function and purpose of claims.

Markman v. Westview Instruments, 52 F.3d 967, 979-80 (Fed. Cir. 1995) (en banc), aff'd, Markman, 517 U.S. 370 979-80 (citations omitted). This heavy reliance on the specification is appropriate due to the Patent and Trademark Office's rules requiring "that application claims must 'conform to the invention as set forth in the remainder of the specification and the terms and phrases used in the claims must find clear support or antecedent basis in the description so that the meaning of the terms in the claims may be ascertainable by reference to the description.'" Phillips, 415 F.3d at 1316-17 (quoting 37 C.F.R. § 1.75(d)(1)). During this analysis, "[i]n examining the specification for proper context, however, this court will not at any time import limitations from the specification into the claims." Innogenetics, N.V. v. Abbott Labs., 512 F.3d 1363, 1370 (Fed. Cir. 2008) (quoting CollegeNet, Inc. v. ApplyYourself, Inc., 418 F.3d 1225, 1231 (Fed. Cir.2005)).

In addition to the claim language and the description within the specification, the prosecution history, which is the "'undisputed public record' of proceedings in the Patent and Trademark Office[,] is of primary significance in understanding the claims." Markman, 52 F.3d at 980. "The prosecution history can often inform the meaning of the claim language by

demonstrating how the inventor understood the invention and whether the inventor limited the invention in the course of prosecution, making the claim scope narrower than it would otherwise be." Phillips, 415 F.3d at 1317. The Federal Circuit restated the basic principles guiding the use of the prosecution history in claim construction in Seachange International, Inc. v. C-Cor Inc., 413 F.3d 1361 (Fed. Cir. 2005):

> in construing the claim, we consider the prosecution history to determine whether the patentee disclaimed or disavowed subject matter, narrowing the scope of the claim terms. In doing so, we examine the entire prosecution history, which includes amendments to claims and all arguments to overcome and distinguish references. Where an applicant argues that a claim possesses a feature that the prior art does not possess in order to overcome a prior art rejection, the argument may serve to narrow the scope of otherwise broad claim language. A disclaimer must be clear and unambiguous.

Id. at 1372-73 (citations omitted).

In addition to the intrinsic evidence discussed above, a court may also rely on extrinsic evidence in interpreting a claim. Phillips, 415 F.3d at 1317. Extrinsic evidence "consists of all evidence external to the patent and prosecution history, including expert and inventor testimony, dictionaries, and learned treatises." Id. (quoting Markman, 52 F.3d at 980 (citing Seymour v. Osborne, 78 U.S. (11 Wall.) 516, 546 (1870))). However, "while extrinsic evidence 'can shed useful light on the relevant art,' . . . it is 'less significant than the intrinsic record in determining 'the legally operative meaning of claim language.'" Phillips, 415 F.3d at 1317. The Federal Circuit cautions courts not to over-rely on extrinsic evidence, highlighting "the flaws inherent in each type of evidence[,]" see id. at 1317-19, and requiring that extrinsic evidence be "considered in the context of the intrinsic evidence," id. at 1319. The Circuit explained the five general

dangers of over-relying on extrinsic evidence in interpreting a claim:

> First, extrinsic evidence by definition is not part of the patent and does not have the specification's virtue of being created at the time of patent prosecution for the purpose of explaining the patent's scope and meaning. Second, while claims are construed as they would be understood by a hypothetical person of skill in the art, extrinsic publications may not be written by or for skilled artisans and therefore may not reflect the understanding of a skilled artisan in the field of the patent. Third, extrinsic evidence consisting of expert reports and testimony is generated at the time of and for the purpose of litigation and thus can suffer from bias that is not present in intrinsic evidence. The effect of that bias can be exacerbated if the expert is not one of skill in the relevant art or if the expert's opinion is offered in a form that is not subject to cross-examination. Fourth, there is a virtually unbounded universe of potential extrinsic evidence of some marginal relevance that could be brought to bear on any claim construction question. In the course of litigation, each party will naturally choose the pieces of extrinsic evidence most favorable to its cause, leaving the court with the considerable task of filtering the useful extrinsic evidence from the fluff. Finally, undue reliance on extrinsic evidence poses the risk that it will be used to change the meaning of claims in derogation of the "indisputable public records consisting of the claims, the specification and the prosecution history," thereby undermining the public notice function of patents.

Id. at 1318-19 (citations omitted). Further, extrinsic evidence should not be relied upon where "an analysis of the intrinsic evidence alone will resolve any ambiguity in a disputed claim term." Vitronics Corp. v. Conceptronic, Inc., 90 F.3d 1576, 1583 (1996); see also Phillips, 415 F.3d at 1324 (further explaining Vitronics language regarding use of extrinsic evidence).

III. DISCUSSION

A. The Meaning of "Unit"

Shire, Corepharma, and Nostrum each propose a different claim construction for the term "unit." Shire proposes that "unit" be construed to mean: "(1) An entity regarded as an

elementary structural or functional constituent of a whole; and (2) an individual, group, structure, or other entity regarded as an elementary structural or functional constituent of a whole." (Shire's Opening Claim Construction Br. 11 [hereinafter Shire Opening Br.].) Corepharma proposes the following construction: "A single thing or entity that is a constituent or isolable member of a more inclusive whole, being the least part of the whole to have a clearly definable existence separate or different from other parts of the whole." (Corapharma's Opening Claim Construction Br. 1-2 [hereinafter Corepharma Opening Br.].) Nostrum does not offer specific language for its proposed construction. Instead, it states that "[a] [u]nit [i]s [a] [d]istinct [p]hysical [s]tructure [c]ontaining [c]arbamazepine [t]hat [i]s [f]ormulated [t]o [h]ave [a] [s]pecific [t]ype [o]f [d]rug [r]elease [p]rofile." (Nostrum Amicus Brief on Claim Construction 15 [hereinafter Nostrum Br.].) The core dispute is whether the term "unit" denotes an independent physical entity or whether it is merely a non-physically separate, functional subdivision of a greater whole.

In analyzing the meaning of "unit" as used in the '570 patent, this Court must address the term in the manner in which the claim language would be understood by "a person of ordinary skill in the art in question at the time of the invention." See Phillips v. AWH Corp., 415 F.3d 1303, 1313 (Fed. Cir. 2005). The parties agree that a person of ordinary skill in the art as applicable to the '570 patent is a highly skilled professional, with Shire proposing, without objection, that such a person has a degree in pharmacy or a similar field and at least two years experience in formulating drug delivery systems. (Shire Opening Br. 13; see Corepharma Opening Br. 17, 21-22; Nostrum Opening Br. 15-24.)

The term "unit" is never individually addressed in any portion of the claim; it is a part of

the other claim language presently under review. The use of "unit" in the two independent claims does not shed significant light on the ordinary meaning of the claim language, namely whether a "unit" is a physical entity; therefore, the full text of the claim, the specification, and the prosecution history must be considered. See Phillips, 415 F.3d at 1314 (citations omitted).

Within independent claim 1, "units" are subparts of a "drug delivery system for the oral administration of carbamazepine. (Fleming Decl. Ex. 1, 8:1-9 (emphasis added).) Claim 18 refers to "a method of treating a patient with carbamazepine" via oral administration of a "composition" containing three different types of "units." (Fleming Decl. Ex. 1, 8:60-68 (emphasis added).) The critical language within independent claims 1 and 18 demonstrates that a "unit" is an element of a means of orally administering carbamazepine wherein three units operate in tandem to create the patented invention. (Fleming Decl. Ex. 1, 8:1-9, 8:60-68.) The "system" in independent claim 1 and the "method" in independent claim 18 are comprised of three parts: "components" (a), (b), and (c), which are identified as an immediate release unit, a sustained release unit, and an enteric release unit. (Fleming Decl. Ex. 1, 8:1-9, 8:60-68.)

Although a presumption exists that dependent claims do not limit the definition of the independent claims, Saunders Group, Inc., 492 F.3d at 1331, the entire patent must be considered, as a person of ordinary skill in the art would not consider the disputed claim term in a vacuum, Phillips, 415 F.3d at 1313. Terms within the dependent claims in the '570 patent demonstrate that the "system" can be in tablet, capsule, or pellet form. (Fleming Decl. Ex. 1, 8:13-23.) The dependent claims also define the composition of the "system" that is described in claims 1 and 18, namely what constitutes the elements of an immediate release unit, a sustained release unit, and an enteric release unit. (Fleming Decl. Ex. 1, 8:13-57.) Of particular note,

dependent claim 15 discusses the amount of each unit present within the system, and dependent claim 16 explains that the sustained release unit and the enteric release unit are coated. (Fleming Decl. Ex. 1, 8:44-56.) Those two dependent claims read,

> 15. A system as in claim **1**, wherein said sustained release unit is present in an amount ranging from about 5.0% to about 25.0% (w/w), said immediate release unit is present in an amount ranging from about 15.0% to about 70.0% (w/w) and said enteric release unit is present in an amount ranging from about 10.0% to about 15% (w/w).
>
> 16. A system as in claim **1**, wherein said sustained release unit is coated with a coating material in an amount ranging from about 1.0% to about 25% (w/w) and said enteric release unit is coated with a coating material in an amount ranging from about 1.0% to about 15.0% (w/w).[1]

(Fleming Decl. Ex. 1, claims 8:44-56.) Dependent claim 15 therefore provides evidence that a "unit" is a physically discrete object, since a weight is given for the amount of each unit present in the total "system" described in claim 1. This is further supported by dependent claim 16, which explains that the enteric release unit and the sustained release unit are coated with a specific weight of coating material. The coating is a physical entity, and it is covering the unit. This provides further evidence that a "unit" is a physical entity.

Although it never defines the term "unit[,]" the specification adds further support to the reading proposed by Corepharma and supported by Nostrum that a unit is "[a] single thing or entity that is a constituent or isolable member of a more inclusive whole, being the least part of the whole to have a clearly definable existence separate or different from other parts of the

[1] "W/W" is defined in the specification: "The term W/W as used herein is representative of a weight to weight ratio of the material specified to the weight of the unit dosage form as a whole." (Fleming Decl. Ex. 1, 2:59-61.)

whole." (Corapharma Opening Br. 1-2.) Within the specification, although a single form is not settled on as the "multiple-unit dosage form[,]" each "unit" is discussed as an individual item that must be coated with a substance:

> For carbamazepine, it is preferred to have three different types of units in a single form multiple-unit dosage form. The first unit is an immediate release dosage form, preferably in pellet form. This component can also be a powder if necessary. In either case, the pellet should have a surface-active agent . . . . Preferably the surface-active agent would be a combination of sodium monoglycerate and sodium lauryl sulfate. The concentration of these materials in this component can range from about 0.05 to about 10.0% (W/W).

(Fleming Decl. Ex. 1, 2:62-3:9.) Finally, the detailed example within the specification refers to each unit having a "pellet" form. (Fleming Decl. Ex. 1, col. 3:10-5:49.) Although a pellet is only a preferred embodiment, the use of that term shows that a "unit" is described throughout the specification as having a structural form; furthermore, the different types of units are shown to have unique properties that distinguish them from one another. (Fleming Decl. Ex. 1, 3:10-5:49.) As the specification is "a written description of the invention that must enable one of ordinary skill in the art to make and use the invention[,]" Markman, 52 F.3d at 979-80, the descriptions of "units" within the specification as being tied to structural entities provides further evidence that the inventor's intent in using the term "unit" was to describe a physically distinct object.

The prosecution history also fails to support a definition of "unit" that is purely functional. Shire cites an August 1993 Amendment to the patent application as defining the terms immediate release unit, sustained release unit, and enteric release unit and supporting a functional construction. (Shire Opening Br. 17-18.) The cited text reads,

> the present invention claims a three unit composition comprised of

- an immediate release unit - which begins to release carbamazepine upon ingestion
- a sustained release unit - which begins to release carbamazepine overtime in the gastro-intestinal tract
- enteric release unit - which provides for delayed release of carbamazepine in the lower gastro-intestinal tract.

(Fleming Decl. Ex. 2, SHCORE000157.) However, the text that follows that statement discusses "the three pellet composition of the present invention[.]" (Id.) Furthermore, the declaration of Dr. Edward M. Rudnic, Ph.D., an inventor of the '570 patent, interchangeably uses the terms "Unit 1 - Immediate Release" with "Pellet A[,]" "Unit 2 - Sustained Release" with "Pellet B[,]" and "Unit 3 - Enteric Release" with "Pellet C[.]" (Fleming Decl. Ex. 2, SHCORE000167.) Additionally, in the Declaration submitted to the Patent and Trademark Office, Dr. Rudnic differentiated his invention from prior art, focusing on the Mehta, Bechgaard, and Khanna patents, and stating that the latter two do not "disclose a three unit composition[,]" and the Mehta patent does not include a sustained release unit, nor does it "disclose the use of carbamazepine." (Fleming Decl. Ex. 2, SHCORE000172-73.) These examples from the prosecution history demonstrate that the inventor understood the use of "unit" within the invention as denoting a physical entity. See Phillips, 415 F.3d at 1317; Seachange Int'l, 413 F.3d at 1372-73.

The discussion above demonstrates that the claim language, the specification, nor the prosecution history suggest that the term "unit" is used to describe a functional approach, as opposed to as a physical description. To the contrary, the claim language, the specification, and the prosecution history more strongly support a claim construction that classifies the '570 patent's use of the term "unit" as representing a physical entity.

Furthermore, extrinsic evidence supports Corepharma's proposed claim construction. Of

particular note is Shire's application and supporting documents for a European Patent for the invention patented by the '570 patent, particularly an April 21, 1998 communication with the European Patent Office ("EPO"). (See Alper Dec. 7, 2007 Decl. Ex. A-C.) Corepharma contends that the April 21, 1998 document constitutes an admission by Shire that "contradicts the claim construction in Shires's Opening and Reply Claim Construction Briefs . . . and confirms the claim construction in Corepharma's Opening and Rebuttal Claim Construction Briefs and the claim construction briefs of *amicus* Nostrum Pharmaceuticals." (Letter from Eric I. Abraham, counsel to Corepharma, to Judge Stanley R. Chesler (Dec. 7, 2007) (docket item #180); Alper Dec. 7, 2007 Decl., Ex. A (Apr. 21, 1998 document).) Shire objects to this interpretation, contending that it is improper for this Court to rely on extrinsic evidence "to rebut the clear intrinsic record[.]" (Letter from Porter F. Fleming, counsel to Shire, to Judge Stanley R. Chesler (Dec. 21, 2007) (docket item #195).) However, while recognizing that extrinsic evidence is accorded less weight than intrinsic evidence, Phillips, 415 F.3d at 1317, this Court is permitted to consider admissions by a party to the EPO as extrinsic evidence. See Gillette Co. v. Energizer Holdings, Inc., 405 F.3d 1367. 1374 (Fed. Cir. 2005) (treating an admission before the EPO as extrinsic evidence). Furthermore, the use of extrinsic evidence is particularly appropriate regarding the '570 patent, since the intrinsic evidence surrounding that patent fails to explicitly define the term "unit[,]" making Shire's description of the invention to a foreign tribunal probative.

Shire's April 21, 1998 submission to the EPO was a "reply to the Communication of October 10, 1997" and contained "a set of new claims 1-19 as a replacement for the claims as filed with the entry into the Regional Phase before the EPO." (Alper Dec. 7, 2007 Decl. Ex. A,

SHCORE094969.) Shire also added to its prior comparison with the Khanna patent, British Patent Number GB-2193632 ("GB-2193632"), to further distinguish the two inventions. (Alper Dec. 7, 2007 Decl. Ex. A SHCORE094969, SHCORE094975.) The claims Shire submitted to the EPO in its April 21, 1998 communication differed in part from those in the '570 patent, but independent claim 1 in both documents is identical. (Fleming Decl. Ex. 1, 8:1-9; Alper Dec. 7, 2007 Decl. Ex. A SHCORE094971.) Further, documents filed with the EPO demonstrate that the '570 patent covers the same invention for which Shire sought protection from the EPO. (See Alper Dec. 7, 2007 Decl. Ex. C, cover page.)

The communication accompanying the April 21, 1998 changes included a statement that the invention for which Shire sought protection from the EPO uses "a combination of different formulations." Shire wrote,

> Also enclosed is a page 1a on which the disclosure of GB-A-2193632 is briefly discussed and which is to be inserted on page 1 after the third paragraph (before the 4th line from the bottom) of the specification as published under the International publication number WO 93/01804.
>
> Since GB-A-2193632 does not disclose an oral dosage form of carbamazepine that serves to deliver carbamazepine over a prolonged period of time by the combination of different formulations . . . this document is deemed to belong to the technological background of the invention.

(Alper Dec. 7, 2007 Decl. Ex. A, SCHORE094969.) The accompanying language that Shire inserted in the patent application explains GB-2193632 and then concludes that, within GB-2193632, "[a] drug delivery system adapted for oral administration of carbamazepine that delivers carbamazepine over a prolonged period of time by employing the combination of different formulations is not disclosed." (Alper Dec. 7, 2007 Decl. Ex. A, SCHORE094975.)

These statements provide evidence of how Shire intended its claim to be understood, specifically that the "units" discussed in the '570 patent are "different formulations." See id. The context in which "formulations" is used denotes an understanding that "units" are physical entities.

The intrinsic evidence provides substantial proof that the '570 patent's use of the term "unit" refers to a physical entity, and that reading is supported by the extrinsic evidence. This Court therefore adopts Corepharma's claim construction that a "unit" is "[a] single thing or entity that is a constituent or isolable member of a more inclusive whole, being the least part of the whole to have a clearly definable existence separate or different from other parts of the whole." (Corapharma Opening Br. 1-2.)

B. The Meaning of "Immediate Release Unit"

The term "immediate release unit" is not defined in the '570 patent's claims. Shire proposes the following claim construction: "[a] functional constituent that begins to release active pharmaceutical ingredient ("API") upon ingestion." (Shire Opening Br. 11.) Corepharma contends that "[a]n 'immediate release unit' is a unit formulated to release the carbamazepine it contains upon ingestion, when the release unit reaches the stomach, and from which release of the API is complete in less than a few hours." (Corepharma Rebuttal Br. 13; Corepharma Opening Br. 28.) Nostrum proposes that the term be construed as "a pellet, powder or other physical form containing carbamazepine that releases carbamazepine upon digestion and having a "PELLET A" dissolution profile as depicted in figure 1 of the '570 patent." (Nostrum Br. 21.)

Despite the absence of a definition for "immediate release" in the patent itself, the term is explicitly defined in the prosecution history. In the August 27, 1993 declaration of Edward M. Rudnic, Ph.D., one of the inventors of the '570 patent, "immediate release unit" is explained as

one "which begins to release the carbamazepine upon ingestion." (Fleming Decl. Ex. 2, SHCORE000172 (Rudnic Decl. filed on Aug. 27, 1993), SHCORE000157 (Aug. 3, 1993 amendment to patent application).)

The definition of "immediate release unit" in the prosecution history, when viewed in light of this Court's claim construction of "unit[,]" "resolves any ambiguity in [the] disputed claim term[.]" Vitronics Corp., 90 F.3d at 1583. Because of the clarity provided by the intrinsic evidence, this Court will not rely on extrinsic evidence to discern the proper claim construction. See id.; Phillips, 415 F.3d at 1324. As such, this Court finds that an "immediate release unit" is a unit, as defined above, which begins to release the carbamazepine upon ingestion.

C. The Meaning of "Sustained Release Unit"

No claim construction is given for "Sustained Release Unit" in the '570 patent. Shire proposes the following: "[a] functional constituent that begins to release API over time in the gastrointestinal tract." (Shire Opening Br. 11.) Corepharma contends that "[a] 'sustained release unit' is a unit formulated with a release rate-controlling coating such that the carbamazepine it contains is released over an extended period of more than a few hours after release begins." (Corepharma Rebuttal Br. 13; Corepharma Opening Br. 29.) Nostrum proposes that the term "sustained release unit" be construed as "a distinct physical object containing carbamazepine that has its own chemical formulation that is designed to release carbamazepine gradually over a period of time in the gastrointestinal tract and having a 'PELLET B' type sustained release dissolution profile such as that depicted in Figure 1 of the '570 patent." (Nostrum Br. 22.)

Despite the differing constructions proposed by the parties, the term "Sustained Release Unit" is explicitly defined in the prosecution history. Dr. Rudnic's declaration and an

amendment to the patent application describe a "sustained release unit" as one "which provides for a gradual release of carbamazepine over time in the gastro-intestinal tract." (Fleming Decl. Ex. 2, SHCORE000172 (Rudnic Decl. filed on Aug. 27, 1993), SHCORE000157 (Aug. 3, 1993 amendment to patent application).)

When the prosecution history is read in light of this Court's claim construction of the term "unit[,]" no ambiguity exits as to the meaning of "sustained release unit." Due to the intrinsic evidence defining the term, extrinsic evidence is not required to discern the proper claim construction. See Vitronics Corp., 90 F.3d at 1583; Phillips, 415 F.3d at 1324. As such, this Court finds that a "sustained release unit" is a unit, as defined above, which provides for a gradual release of carbamazepine over time in the gastro-intestinal tract.

D. The Meaning of "Enteric Release Unit"

"Enteric Release Unit" is not defined within the '570 patent's claims. Shire proposes the following claim construction: "A functional constituent that provides for delayed release of API in the gastrointestinal tract." (Shire Opening Br. 11.) Corepharma contends that "[a]n 'enteric release unit' is a unit formulated with pH sensitive material to delay release of substantially all of the carbamazepine it contains until it reaches the lower gastro-intestinal tract of the patient." (Corepharma Rebuttal Br. 13-14; Corepharma Opening Br. 30.) Nostrum proposes that the term "enteric release unit" be construed as "a distinct physical object containing carbamazepine that has its own chemical formulation that is designed to delay breaking down and releasing carbamazepine until the unit reaches the pH in the lower gastrointestinal tract and having a dissolution profile such as that depicted in the "PELLET C" curve in Figure 1 of the '570 patent." (Nostrum Br. 24.)

In the prosecution history, "enteric release unit" is described in a 1993 amendment to the patent application as a unit "which provides for a delayed release of carbamazepine in the lower gastro-intestinal tract." (Fleming Decl. Ex. 2, SHCORE000157 (Aug. 3, 1993 amendment to patent application).) Of note, it is also described in the same way by Dr. Rudnic, however, he refers to an "enteric release pellet[,]" as opposed to an "enteric release unit[.]" (Fleming Decl., Ex. 2, SHCORE000172 (Rudnic Decl. filed on Aug. 27, 1993).)

The prosecution history, when read in light of this Court's definition of "unit[,]" resolves any ambiguity as to the meaning of "enteric release unit[,]" obviating the need to rely on extrinsic evidence in defining the term. See Vitronics Corp., 90 F.3d at 1583; Phillips, 415 F.3d at 1324. This Court therefore determines that the proper claim construction for the term "enteric release unit" is a unit, as defined above, which provides for a delayed release of carbamazepine in the lower gastro-intestinal tract.

IV. CONCLUSION

This Court has examined the disputes over construction of four claim terms raised by the parties and, for the reasons stated above, resolves these disputes by rejecting the limitations proposed by Shire on the term "unit" and also rejecting the limitations proposed by Corepharma and Nostrum on the terms "immediate release unit[,]" "sustained release unit[,]" and "enteric release unit[.]" The disputed terms are construed as being physical entities, as proposed by Corepharma and Nostrum, but the definitions of "immediate release unit[,]" "sustained release unit[,]" and "enteric release unit" are broader than the constructions proposed by Defendants.

Specifically, the central disputes are resolved as follows.

The term "unit" in claims 1 and 18 of the '570 patent shall be construed in all future

proceedings, pursuant to Markman v. Westview Instruments, Inc., 52 F.3d 967 (Fed. Cir. 1995), as a single thing or entity that is a constituent or isolable member of a more inclusive whole, being the least part of the whole to have a clearly definable existence separate or different from other parts of the whole.

The term "immediate release unit" in claims 1 and 18 of the '570 patent shall be construed in all future proceedings, pursuant to Markman, 52 F.3d 967, as a unit, as defined above, which begins to release the carbamazepine upon ingestion.

The term "sustained release unit" in claims 1 and 18 of the '570 patent shall be construed in all future proceedings, pursuant to Markman, 52 F.3d 967, as a unit, as defined above, which provides for a gradual release of carbamazepine over time in the gastro-intestinal tract.

The term "enteric release unit" in claims 1 and 18 of the '570 patent shall be construed in all future proceedings, pursuant to Markman, 52 F.3d 967, as unit, as defined above, which provides for a delayed release of carbamazepine in the lower gastro-intestinal tract.

An appropriate form of order will be filed together with this Opinion.

s/ Stanley R. Chesler
STANLEY R. CHESLER
United States District Judge

DATED: March 26, 2008